



## TRANSMITTAL FORM

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Total Number of Pages in This Submission

8

Application Number	10/714,211
Filing Date	11/14/2003
First Named Inventor	ZAHNER, Joseph E.
Art Unit	1632
Examiner Name	WOITACH, Joseph T.
Attorney Docket Number	NR 03-001

### ENCLOSURES (Check all that apply)

- |   |  |   |
|---|--|---|
| <input checked="" type="checkbox"/> Fee Transmittal Form<br><input type="checkbox"/> Fee Attached<br><input checked="" type="checkbox"/> Amendment/Reply<br><input type="checkbox"/> After Final<br><input type="checkbox"/> Affidavits/declaration(s)<br><input type="checkbox"/> Extension of Time Request<br><input type="checkbox"/> Express Abandonment Request<br><input checked="" type="checkbox"/> Information Disclosure Statement<br><br><input type="checkbox"/> Certified Copy of Priority Document(s)<br><input type="checkbox"/> Reply to Missing Parts/<br>Incomplete Application<br><input type="checkbox"/> Reply to Missing Parts<br>under 37 CFR 1.52 or 1.53 | <input type="checkbox"/> Drawing(s)<br><input type="checkbox"/> Licensing-related Papers<br><input checked="" type="checkbox"/> Petition<br><input type="checkbox"/> Petition to Convert to a<br>Provisional Application<br><input checked="" type="checkbox"/> Power of Attorney, Revocation<br>Change of Correspondence Address<br><input type="checkbox"/> Terminal Disclaimer<br><input type="checkbox"/> Request for Refund<br><input type="checkbox"/> CD, Number of CD(s) _____<br><input type="checkbox"/> Landscape Table on CD | <input type="checkbox"/> After Allowance Communication to TC<br><input type="checkbox"/> Appeal Communication to Board<br>of Appeals and Interferences<br><input type="checkbox"/> Appeal Communication to TC<br>(Appeal Notice, Brief, Reply Brief)<br><input type="checkbox"/> Proprietary Information<br><input type="checkbox"/> Status Letter<br><input checked="" type="checkbox"/> Other Enclosure(s) (please identify<br>below):<br>Return Reply Postcard |
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Remarks

### SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Joseph E. Zahner		
Signature			
Printed name	Joseph E. Zahner		
Date	January 16, 2007	Reg. No.	pro se

### CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature			
Typed or printed name	Joseph E. Zahner	Date	January 16, 2007

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Effective on 12/08/2004.

Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

**FEE TRANSMITTAL**  
**For FY 2006**☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) 180.00

**Complete if Known**

Application Number	10/714,211
Filing Date	11/14/2003
First Named Inventor	ZAHNER, Joseph E.
Examiner Name	WOITACH, Joseph T.
Art Unit	1632
Attorney Docket No.	NR 03-001

**METHOD OF PAYMENT (check all that apply)**☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): \_\_\_\_\_☒ Deposit Account Deposit Account Number: 503293 Deposit Account Name: SLUTechTransfer

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, except for the filing fee☐ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 ☐ Credit any overpayments

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**FEE CALCULATION****1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

**2. EXCESS CLAIM FEES****Fee Description**

Each claim over 20 (including Reissues)

Fee (\$)	Small Entity Fee (\$)
50	25
200	100
360	180

Each independent claim over 3 (including Reissues)

Multiple dependent claims

<b>Total Claims</b>	<b>Extra Claims</b>	<b>Fee (\$)</b>	<b>Fee Paid (\$)</b>
- 20 or HP =	x	=	

HP = highest number of total claims paid for, if greater than 20.

<b>Indep. Claims</b>	<b>Extra Claims</b>	<b>Fee (\$)</b>	<b>Fee Paid (\$)</b>
- 3 or HP =	x	=	

HP = highest number of independent claims paid for, if greater than 3.

**3. APPLICATION SIZE FEE**

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

<b>Total Sheets</b>	<b>Extra Sheets</b>	<b>Number of each additional 50 or fraction thereof</b>	<b>Fee (\$)</b>	<b>Fee Paid (\$)</b>
- 100 =	/ 50 =	(round up to a whole number) x	=	

**4. OTHER FEE(S)**

Non-English Specification, \$130 fee (no small entity discount)

Other (e.g., late filing surcharge): IDS 37 CFR 1.97 (c)(2) and 1.17(p)

**Fees Paid (\$)**

180.00

**SUBMITTED BY**

Signature	Registration No. (Attorney/Agent) 48,224	Telephone (314) 977-7731
Name (Print/Type) Joseph E. Zahner		Date January 16, 2007

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

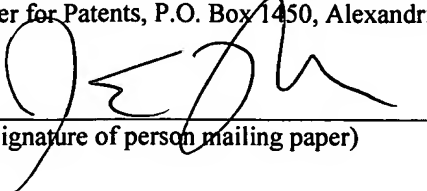
Date January 15, 2007

Docket No. NR 03-001

**CERTIFICATION UNDER 37 CFR 1.8**

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Joseph E. Zahner  
(Typed name of person mailing paper)

  
(Signature of person mailing paper)

Transmitted herewith for filing is an amendment and related papers for:

<b>Application of:</b>	Joseph E. Zahner	<b>Art Unit:</b>	1632
<b>Serial No.:</b>	10/714,211	<b>Atty. Docket No.:</b>	NR 03-001
<b>Filed:</b>	11/14/2003		
<b>For:</b>	In-vitro-derived adult pluripotent stem cells and uses therefor	<b>Examiner:</b>	Joseph T. Voitach

**RESPONSE TO OFFICIAL ACTION**

In the present Official Action, which is dated 10/19/2006, Examiner's position is that pending claims 1-12 are rejected under 37 CFR 112 as not being enabled. Essentially, Examiner hangs his contention around the assumptions that "(t)he working example demonstrates that outer root cell treated with retinoic acid take on a morphology which appears to be neuron-like, however this is based on morphology and no specific neuronal markers are demonstrated. Except for the specific conditions set forth in the working examples, the specification provides no other specific conditions for the isolation or culturing conditions for other cell types," (Official Action, page 5, lines 3-7).

Applicant asserts that Examiner is in error in his assumption that only morphology data is shown to support the fact that the keratinocytes were reprogrammed according to the method described in detail in the specification. Both morphological and molecular marker data demonstrate successful reprogramming. Figure 2 shows that the population of reprogrammed keratinocytes express mRNAs associated with cell-types different than keratinocytes. Paragraphs [0096] and [0164]

describe the increase in neurofilament mRNA of 89% above levels detected in keratinocytes. Neurofilament represents a cell-type associated with the ectodermal lineage. An increase in molecular markers for endodermal descendent cells, e.g., alpha 1 antitrypsin, and mesodermal descendent cells, e.g., cardiac actin, is demonstrated by RT-PCR performed on reprogrammed cells (see again paragraphs [0096] and [0164], as well as Figure 2). Thus, Applicant contends that specification describes in sufficient detail to enable the treatment of adult keratinocytes that results in the expression of non-keratinocyte genes that represent ectodermal, mesodermal and endodermal –lineage derived cells.

Examiner also contends that “the specification provides no other specific conditions for the isolation or culturing conditions for other cell types.” Applicant’s position is that the contention is moot, given that the instant claims are specifically directed to the reprogramming of keratinocytes and do not claim any other cell types.

Examiner also takes the position that the instant claims are overly broad in that the specification lacks “specific guidance necessary to practice the instantly claimed invention in its full breadth. In particular the breadth of the claim encompasses ‘re-programming’ the keratinocyte into any cell type, totipotent, pluripotent, or any differentiated cell type.” Applicant respectfully points out that the original (instant) claim 1 is directed not to a “any cell type, totipotent, pluripotent, or any differentiated cell type,” but rather to a “reprogrammed cell (that) expresses a telomerase gene product and is capable of expressing a gene product which is not expressed by a keratinocyte,” (claim 1.) The specification clearly discloses the treatment of adult keratinocytes with chromatin affecting agents, which resulted in the elevated expression of hTERT mRNA (telomerase gene product), as depicted in Figure 2, treatment regimen 2, and paragraph [0163], which describes an increase of 198% in telomerase gene expression (mRNA as determined by RT-PCR as described) over telomerase expression in the untreated adult keratinocytes.

Furthermore, the “capab(ility) of expressing a gene product which is not expressed by a keratinocyte” is demonstrated by treating the reprogrammed keratinocytes with retinoic acid, a known non-specific inducer of differentiation. That treatment resulted in the expression of the non-keratinocyte gene products neurofilament, cardiac actin and alpha 1 antitrypsin, as determined by RT-PCR (Figure 2). Thus, each element of claim 1 is supported by concrete examples provided in the specification.


Examiner also provides an argument in support of the position that the literature provides a “complex story” of changes in methylation and acetylation as it relates to cell differentiation. Applicant acknowledges and supports the contention that the prior art does not sufficiently support the use of agents that affect changes in methylation and acetylation to reprogram a cell to have pluripotency. However, the fact remains that Inventor has disclosed in the examples a process for treating at least a keratinocyte with agents that affect changes in methylation and acetylation, and has disclosed gene expression data in evidence of a reprogrammed cell capable of expressing gene products representative of ectoderm (neurofilament), mesoderm (cardiac actin) and endoderm (alpha 1 antitrypsin). These are real results observed by Inventor and disclosed in sufficient enabling detail for a skilled cell or developmental biologist to practice the claimed invention.

In view of the direct evidence provided in the specification and the highlighting of those particular details in support of arguments against Examiner’s contentions, Applicant respectfully requests that the rejection of the claims be withdrawn and the claims allowed to issue.

Applicant also wishes to thank Examiner for stating in the conclusion of the instant official action that “(t)he claims are free of the art of record ... (and that) there is no specific teaching nor motivation to treat keratinocyte in such a way to provide for a re-programmed cell.”

Applicant believes that this response is complete. Should any issues made in the official action remain as not addressed, Examiner is invited to call or e-mail the undersigned Applicant.

Respectfully submitted,



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